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Documents Management Branch
Food and Drug Administration
HFA-305
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

1 October, 1999

Re: Comments On Docket No. 99D-2013; Guidance for Industry- Cooperative Manufacturing Arrangements for Licensed Biologics

Dear Sir/Madam:

Procter & Gamble Pharmaceuticals wishes to thank the agency for the opportunity to review the above draft guidance. We recognize the fact that a considerable effort has been placed in drafting this document and that this document should be very helpful to industry in providing principles for sharing or contracting manufacturing of licensed biologics.

We have reviewed the draft guidance and have the following comments and suggestions (as attached).

If there are any questions or if I can be of further assistance, please feel free to call me at (513) 622-1811.

Sincerely,

Gopi K. Vudathala, Ph.D

Senior Scientist, Regulatory Affairs

99D-2013

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Please Note: Headers, Titles, Outline Captions, and blank lines are not included in the line count. Italicized print is verbage taken directly from the guidance.

Page/ Line	Statement / Comment Description
1 / 4	*. . .sharing* ***or contracting parts of manufacturing . . to facilitate development..*** . Contract Manufacturing should not be limited to the-development phase. One driver for contracting parts of manufacturing is the lack of expertise in the area by the Manufacturer/product license holder. This wording may be interpreted too literally.
1 / 9	***. . .this guidance applies to product approved with a PLA..*** . This may imply that the development and manufacture under an IND for clinical trials are not covered by the guidance. This is contradictory to the statement found in comment 1 / 4 above and also could be interpreted too literally.
3 / 20	***. . . divided manufacture should be submitted as*** a ***supplement..*** . This should be revised to allow for the flexibility of being contained in the initial filing or in a supplement.
3 / 27	***. .ability to demonstrate acceptable methods for handling..*** .These items would be found in internal documentation and/or supply agreements. These are considered systems' items that would be explored during inspections and therefore should not be required as an integral part of the license application.
5 / 17-20	*Applications* ***for*** *an* ***intermediate product..*** *.license* ***should contain..*** *.criteria* ***used for lot*** *by* ***lot*** *acceptablity...including* ***sterility (or bioburden), stability, product characterization,*** *potency, and* ***purity specifications..*** .The stated needs for an intermediate product are not appropriate as this level of characterization and testing are only performed on the final product. The statement that follows in the text is appropriate and should be adequate to ensure that the intermediate product will meet its established quality specifications.
7 / 6	***The contract manufacturer should a/so share with the applicant..*** *.(including*

	introduction of new products);...Most companies treat this information as highly confidential and proprietary, based on confidentiality agreements signed between the contract manufacturer and the sponsor. So, providing this information to another sponsor may not always be feasible.
7 / multi	***. . .the license applicant..*** It may be beneficial to specify that it is the product license applicant or (PLA), to differentiate from the other licenses discussed periodically in this document (ELA and BLA). [this occurs in multiple places from page 7 to end of document]
8 / 22	*...the applicant's license application should ...list of all standard operating* ***procedures..*** .This requirement is referring to systems; systems should not be part of an application or filing document. They should be covered under CGMPs and audits.
9 / 1	*A description of the product shipped to the contract facility*....It is suggested that this statement be revised to state: 'to or from the contract facility'.
9 / 8	*..including introduction of additional marketed products and clinical material* processing operations.. .Although it is appropriate for the contract facility to inform the license applicant of all proposed changes in manufacturing and facilities prior to implementation, introduction of additional marketed products and clinical material processing operations may be considered proprietary and not revealed by the contract manufacturer.

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